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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/214,047 | 07/12/99 | MULLER D | M-1492 |

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| EXAMINER | |
|---|---|
| SHARAREH,S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1619 | 16 |

**DATE MAILED:** 07/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/214,047 | Applicant(s) Muller, Dieter |
|---|---|---|
| | Examiner SHAHNAM SHARAREH | Art Unit 1619 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 2/7/01, 5/4/01 .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1 and 3-5 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

### *Request for Continued Examination*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 04, 2001 and February 07, 2001 have been entered.

### *Status of the Claims*

2. Claims 1, 3-5 are now pending.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "pharmaceutical administration form in form of an electromagnetic memory" is vague, because in the pharmaceutical art "a pharmaceutical administration form" is considered a dosage form that is administrable by any of the known routes of administration. In the instant case "an electromagnetic memory" considered as a pharmaceutical form is indefinite

because it does not constitute a pharmaceutical form. Second, it is not clear what is encompassed by "a pharmaceutical administration form". The metes and bounds of such recitation is not clear.

The recitation of "bioresonance spectrum" is indefinite. The specification further fails to clearly define what a bioresonance spectrum is? The definition set forth in page 2 of the specification is ambiguous.

5. Claim 3 is vague. It is not clear what is meant by "to a skin well-tolerated adhesive tape whose projecting marginal strips are suited to be adhered to the skin of a patient." what are the metes and bounds of " well-tolerated adhesive tape" or "suited to be adhered to skin"? Furthermore, parenthetical references to the drawings is renders the claims indefinite, because the claims must stand on their own.

6. Claims 4-5 respectively recite the limitations "predetermined factor" and "predetermined amplification." Such recitations appear to be relative, the metes and bounds of which is not clear.

7. Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear for treatment of what type of disease is the instant pharmaceutical form used for, or what type of steps are required to utilize the instant method of therapy.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 3-5 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using a bioresonance unit to create a magnetic tape, does not reasonably provide enablement for methods of making or using a pharmaceutical administrable form for treating various disease states. Furthermore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

In particular, the specifications fails to enable the skilled artisan to practice the invention without undue experimentation. As held by *ex parte Forman* (230 USPQ 546, BdPatApp & Int.) and *In re Wands* (858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988) provide several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation.

First, the state of the prior art concerning methods of bioresonance therapy is controversial and speculative. In fact, the proponents of such alternative therapy believe that the physical science is the science of dead material and thus incapable of commenting on the effects of biological phenomena such as bioresonance therapy or other methods of acupuncture in treatments of various disease states. Furthermore, the pharmacological effects and benefits of such types of therapeutic approaches have not been described by scientific methodologies. (Schoni p. 285)

Therefore, the specification does not provide adequate enablement for the claimed therapeutic utility of the instant invention.

Second, there is no correlation between the instantly claimed bioresonance spectrum and those described in the art. It has been described in the homeopathic art that in bioresonance therapy "the pathological electromagnetic wave patterns" which is different for specific disease state are corrected when converted to "normalized electromagnetic waves", using a specific analyzing apparatus such as BIOCOM ™. Accordingly, the waves from one part of the body are taken up by a brass electrode, and analyzed in a separator of said apparatus. During this process, the pathological waves are separated from the normal (healthy) waves and then said pathological waves are reversed electronically by said separator and finally transmitted back to the patient by an exit electrode to produce its therapeutic effects (see Schoni et al, Int Arch Allergy Immunol... 1997;12:238-246).

Hence, the bioenergy that is normalized during a treatment course of bioresonance therapy is actually generated within the body of the patient, and then corrected by an external apparatus. (see Schoni et al p.245, and specification page.5). In fact, the recitation of "bioresonance" requires the element of "bio" referring to biology or a biological entity conveying a direct association of the intended resonance with a living organisms. Therefore, there is no correlation between applying the bioresonance spectrum obtained of a medical compound (a dead entity) and its effects on a biological receptor system, because this approach, in itself, is in contrary to the principles of the bioresonance theory.

Further, there is no predictability in the art that said bioresonance spectrum obtained in the form of a magnetic tape can correct the pathological waves of a patient (as in accord with the bioresonance theory), neither is there any predictability in the mechanism of action of said spectrum on biological and cellular receptors. specification is silent about how such spectrum can influence the internal receptor system and improve a diseased tissue. In addition, there is no prior knowledge in the art explaining the normal frequency of human's bioenergy, thus, one skilled in the art would not be able to determine the efficacy of such therapy without undue experimentation.

Finally, the working examples do not provide any scientific guidance of how the instant pharmaceutical form exerts its pharmacologic benefits on the receptor system. In fact, the bioresonance therapy, as reported by Schoni et al, has revealed no therapeutic effects neither in the short- nor in the long-term management of specific skin allergy or atopic dermatitis in children (see abstract.) The specification does not provide guidance as to how one skilled in the art would go about treating a specific diseases within the scope of the presently claimed invention. Nor is any guidance provided to a specific protocol that can be utilized in order to prove the efficacy of the presently claimed pharmaceutical form in treating the claimed disease states. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention. Thus, the specification does not enable any person skilled in the art to make and use the invention and further practice it within the scope that is instantly claimed.

Applicant's arguments in the response filed on February 7, 2001, Paper No. 11, has been fully considered. Applicant argues that dead material are described in Fur Holopathische Medizin to provide bioresonance, namely when processed by Quint system. However, Applicant has failed to provide any evidence as to the extent of his claim. Furthermore, such argument is not the basis for enablement. Merely because an article describes the presence of a spectrum obtained from a chemical compound in the form of electromagnetic energy, does not amount to enabling the instantly claimed therapeutic efficacy. Accordingly, claims 1, 3-5 stand rejected.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Berner et al DE 3419055.

The instant claim is directed to a pharmaceutically administrable form comprising a bioresonance spectrum of a medical compound. Further the instant claim appears to be drafted in the form of a product-by-process claim.

Product-by-process claims are not limited to their process methods. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In the instant case, Brenner disclose sa magnetic foil sheet for biophysical therapy comprising plastic matrix and magnetic particles (see abstract.) Therefore, Brenner meets the limitations set forth in the instant claim.

12. Claims 1, 3 and 5 rejected under 35 U.S.C. 102(b) as being anticipated by Whitson-Fischman US Patent 5,162,037.

The instant claims are directed to a pharmaceutically administration form comprising bioresonance spectrum of a medical compound in a magnetic tape, and methods of using said administration form in treatment of various disease states. The instant product claims appear to be drafted in the form of a product-by-process claim.

Product-by-process claims are not limited to their process methods. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Whitson-Fischmann discloses methods of impregnating a topical patch comprising a homeopathic medicament and a magnetically permeable ingredient that is magnetized (see abstract, col 6 lines 35-68, col 7 lines 1-30). Whitson-Fischmann further discloses methods of using his patch by aligning it near a selected acupuncture point on the patient's skin (see col 9

lines 29-61, col 40 lines 16-40.) Thus, Whitson-Fischmann meets the limitations set forth in the instant claims.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

13. Claims 1, 3-5 rejected under 35 U.S.C. 102(e) as being anticipated by Dillinger et al US Patent 5,830,140

Dillinger et al discloses the use of a bioresonance apparatus to register the substance specific or body specific energetic information in the form of electromagnetic spectra to produce a homeopathic medicament composition (see col 1 lines 1-65, col 3 lines 40-67, col 4 lines 65-67). Dillinger discloses that the characteristic oscillation information after processing through the bandpass filter can be superimposed on an oscillating 10Hz magnetic field from the generator (see col 7, lines 1-5; col 7, lines 20-35). Therefore, Dillinnger discloses the instant frequency ranges. Accordingly, Dillinger et al meet the limitations set forth in the instant claims.

***Conclusion***

14. No claims are allowed. This is a continuation of applicant's earlier Application No. 09/214047. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

*sjs, 7/3/2001*

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